

K072256

## 510(k) SUMMARY

For

Hill Laboratories

**HF54 Combination Ultrasound Interferential and Premodulated Stimulation  
System with optional hands-free operation**

### 1. Submitter's Name and Address

Submitter's Name: Hill Laboratories  
Address: 3 Bacton Hill Rd  
City, State, and Zip: Frazer, PA 19355

**MAR 12 2008**

### 2. Contact Person

Name: Brady Aller  
Title: Sales/Service Manager  
Telephone: ( 610 ) 644-2867  
Facsimile: ( 610 ) 647-6297  
E-mail: bradyaller@hilllabs.com

### 3. Manufacturing Facility Address

Manufacturer: Hill Laboratories  
Address: 3 Bacton Hill Rd  
City, State, and ZIP: Frazer, PA 19355

### 4. Establishment Registration Number

Establishment Registration Number: 2510425

### 5. Reason for Submission

Expanded Indications for Use

### 6. Device Details

Proprietary or Trade Name: HF54 Combination Ultrasound Interferential and Premodulated Stimulation System with optional hands-free operation  
Common Name: Ultrasonic Diathermy

**7. Device Common Name, Classification, Product Code & CFR No.**

Common Name	Class	ProCode	CFR
Ultrasonic Diathermy	2	IMI	890.5300
Interferential Current Therapy	2	LIH	
Infrared lamp	2	ILY	890.5500

**8. Classification Name**

- (i) diathermy, ultrasonic, for use in applying therapeutic deep heat
- (ii) interferential current therapy
- (iii) lamp, infrared, therapeutic heating

**9. Device Classification Panel**

Physical Medicine & Neurology

**10. Indications for Use**

**10.1 Interferential and Premodulated Modes**

Pain relief for:

- Symptomatic relief of chronic intractable pain and/or management of traumatic or post surgical pain.

**10.2 Ultrasound Therapy**

Ultrasound therapy is available from the HF54 and indicated for:

Applying therapeutic deep heat within body tissues for the treatment of selected chronic and sub-chronic medical conditions such as:

- Relief of pain
- Joint contractures

This can be done using One or two ultrasound applicators. The second ultrasound applicator is optional.

Ultrasound therapy, either alone or in combination with interferential therapy or premodulated therapy can be used in a scanned manner (where the therapist moves the applicator) or for specific treatment areas identified in the operator's manual, the applicator can be used in a hands-free manner (where the applicator remains stationary).

**10.3 Infrared Therapy**

An Infrared light probe is available as an optional accessory (HF023) for use with the Hill Laboratories HF54 Combination Ultrasound Interferential and premodulated stimulation system or with an optional external medical grade, isolated power supply.

It is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

## 11. Standards

### 11.1 Mandatory Standards

21 CFR 1050.10 is applicable to therapeutic ultrasound. The HF54 Combination Ultrasound Interferential and Premodulated Stimulation System with optional hands-free operation complies with this mandatory standard.

### 11.2 Consensus Standards

The HF54 Combination Ultrasound Interferential and Premodulated Stimulation System with optional hands-free operation is designed to comply with the following Consensus Standards:

STANDARD NO.	TITLE
IEC 60601-1 +A1, +A2	Medical Electrical Equipment- Part 1: General Requirements for Safety
UL 60601-1	Medical Electrical Equipment- Part 1: General Requirements for Safety
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-5	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-10	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators

## 12. Predicate Devices

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Class
K062256	HF 54	Hill Laboratories	2

## **12.1 Substantial Equivalence (SE) Rationale**

### **12.1.1 Technology**

The HF54 with optional hands-free operation offers the same electrical stimulation, ultrasonic therapy and/or combination of the two and shares the same characteristics including waveforms, operating frequencies and the same use in physical medicine and neurology as the predicate device. The device with its proposed extended indications for use is intended to be used only by a qualified therapist.

### **12.1.2 Standards**

The ultrasound output and electrical stimulation currents are consistent with FDA guidance and international standards. The new device is in compliance to the same standards.

### **12.1.3 Materials**

The materials used in construction of the device and the method of information display are identical. The measured parameters for the proposed HF54 are the identical to those displayed on the device cleared under K062256. The software has not been changed from the cleared device.

### **12.1.4 Risk Analysis**

The expanded indications for use (stationary ultrasound) needed a review of the risks posed by a stationary technique. The primary risks were identified as:

- a) Temperatures in tissues above 45 °C
- b) Temperature rise in bone
- c) Standing waves
- d) Self-heating of the ultrasound applicator
- e) The patient falling asleep during hands-free operation possibly leading to overheating of tissues.

#### **12.1.4.1 Temperatures in Tissues and In Bone**

From Measurement and Thermal Index Calculations, it was shown that with an intensity of  $\leq 10W$ , the temperature of Tissue or Bone would not rise above 45 °C when used as directed. See Attachment C-1. There is no new safety issue.

#### **12.1.4.2 Standing Waves**

The ultrasound output is pulsed and will not support standing waves. There is no new safety issue.

#### **12.1.4.3 Self Heating of the Ultrasound Applicator**

Measurements made during the original submission for the HF54 included thermal measurements of the ultrasound applicator surface. The tests demonstrated that the applicator surface temperature did not exceed 45 °C when stationary, over the whole treatment time. Measurements were made at equal distances across the surface of the treatment surface. There is no new safety issue.

#### **12.1.4.4 Patient falling asleep during treatment**

The operator's manual requires that the operator remain in the same area as the patient and must monitor the patient to ensure that the patient has not fallen asleep.

There are no new treatment modes, identical circuitry and software are used. The changes therefore do not change the effectiveness of the device.

## **12.2 Conclusion**

The proposed HF54 with Optional Hands-free operation when used as directed in the operator's manual presents no new safety or effectiveness concerns and is Substantially Equivalent to the current version of the HF54 cleared under K062256.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 5, 2014

Hill Laboratories  
c/o Mr. Brady Aller  
3 Bacton Hill Rd.  
Frazer, PA 19355

Re: K072256  
Trade/Device Name: HF54 Combination Ultrasound Interferential and Premodulated  
Stimulation System with optional hands-free operation  
Regulation Number: 21 CFR 890.5300  
Regulation Name: Ultrasonic Diathermy  
Regulatory Class: II  
Product Code: PFW; ILY; LIH  
Dated: December 10, 2007  
Received: December 13, 2007

Dear Mr. Aller:

This letter corrects our substantially equivalent letter of March 12, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joyce M. Whang -S**

for Carlos Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) No.  
If known \_\_\_\_\_

**Indications For Use statement – Interferential and Premodulated Modes**

Device Name: HF54 Combination Ultrasound Interferential and Premodulated  
Stimulation System with optional hands-free operation

Indications For Use:

The HF54 interferential therapy and premodulated therapy is indicated for:

Pain relief for:

Symptomatic relief of chronic intractable pain and/or  
management of traumatic or post surgical pain.

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Prescription Use   X   AND/OR  
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart  
C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Osh for mxx  
(Division Sign-off)  
**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K072256

510(k) No.  
If known \_\_\_\_\_

### Indications For Use statement – Ultrasound Therapy

Device Name: HF54 Combination Ultrasound Interferential and Premodulated Stimulation System with optional hands-free operation

Indications For Use:

Ultrasound therapy is available from the HF54 and indicated for:  
Applying therapeutic deep heat within body tissues for the treatment of selected chronic and sub-chronic medical conditions such as:

Relief of pain

joint contractures

This can be done using One or two ultrasound applicators. The second ultrasound applicator is optional.

Ultrasound therapy, either alone or in combination with interferential therapy or premodulated therapy can be used in a scanned manner (where the therapist moves the applicator) or for specific treatment areas identified in the operator's manual, the applicator can be used in a hands-free manner (where the applicator remains stationary).

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Prescription Use X AND/OR  
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil P. Ogle, M.D.  
(Division Sign-Off,  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K07225C

510(k) No.  
If known \_\_\_\_\_

### Indications For Use statement –Infrared Applicator

Device Name: Infrared Therapy (using optional HF023)

Indications For Use:

An Infrared Therapy Probe is available as an optional accessory (HF023) for use with the Hill Laboratories HF54 Combination Ultrasound Interferential and premodulated stimulation system or for stand-alone use with an optional external medical grade, isolated power supply. It is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

Prescription Use X AND/OR  
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Neil Ogden for me*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K072256